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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,601	05/25/2006	Matthias Austen	WEICKM-0058	1728
7590 09/15/2010 Millen, White, Zelano & Branigan Arlington Courthouse Plaza 1 2200 Clarendon Boulevard, Suite 1400 Arlington, VA 22201			EXAMINER CROUCH, DEBORAH	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 09/15/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,601

Applicant(s)

AUSTEN ET AL.

Examiner

Deborah Crouch

Art Unit

1632

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 18, 24, 25, 42, 44-63 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-74 is/are rejected.
- 7) ☒ Claim(s) 10 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/16/10.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Applicant's arguments filed July 16, 2010 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-74 are pending. Claims 13, 14, 18, 24, 25, 42, 44-63 and 67 are withdrawn from examination as directed to a non-elected invention. Claims 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-74 are examined herein.

Prosecution of this application has been transferred to Deborah Crouch, Ph.D., AU 1632. Contact information for Ex. Crouch can be found at the end of this office action.

Rejections or objections made in the office action mailed February 16, 2010 under improper incorporation by reference, 35 U.S.C. § 112, first parag. Written description and 35 U.S.C. § 112, second paragraph have been withdrawn. Any other rejections not repeated in the present office action have also been withdrawn. In an attempt of clarity, the present examiner is maintaining only the rejection made under 35 U.S.C. § 112, first parag., scope of enablement.

Restriction/Election

Applicant continues to argue the merits of the restriction/election requirement mailed November 28, 2008. However, since the restriction/election was made final in the last office action, the proper course of action now is to petition for review by the TC1600 Director.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-72 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for an *in vitro* method for stimulating and/or inducing insulin production in differentiated ES cells, comprising obtaining embryonic stem (ES) cells transformed to constitutively expressing a Pax4 gene, and differentiating said Pax-4 expressing cells in the presence of neurturin polypeptide, to produce differentiated insulin producing cells; does not reasonably provide an enablement for a method of inducing the differentiation of any type of progenitor cells from any source or progenitor cells transfected with any pancreatic gene, to produce insulin producing cells that further express neurturin, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is based on issues related to the absence of an enabling disclosure for the ability to differentiate and induce insulin production via any type of progenitor cell, or to promote protection, survival or regeneration of insulin producing cells, using neurturin or variants thereof, or modulators or effectors thereof. In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404:

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

MPEP § 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the

evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection.”

In summary, the working examples do not provide an enablement for promoting the protection, survival and/or regeneration of insulin producing cells by contacting such cells with neurturin or its modulators or effectors. Moreover, the specification provides no examples of modulators or effectors of neurturin polypeptide.

Withdrawn Rejections

1. The scope rejection regarding variants, modulators and effectors is withdrawn.

Applicant argues Johnson was filed seven years prior to the present application and rapid progress had been made in the post-genomic era. Wobus, applicant argues, examines the ability of various genes/proteins to differentiate stem cells into insulin producing cells, and thus supports applicant's invention. These arguments are not persuasive.

The enablement rejection limits the claims to an in vitro method of inducing ES cells expressing a Pax-4 gene to express insulin. The rejection is based on a lack of predictability of inducing expression of insulin in stem cells in vivo. Applicant has not pointed to any post-filing art to support enablement of the in vivo aspect of the claims, post-filing art that overcomes Johnson or provides evidence that Wobus's disclosure is enabling for in vivo aspects. Without such arguments, the rejection of record is maintained.

Applicant refers to Delong (2002), Door (2008), Nu (2008), Bonner-Weir (2000) as well as others to support their arguments that populations of progenitor cells are present in mouse pancreas that can regenerate into new endocrine cells. These arguments are not persuasive.

Each reference is to an in vitro assay and/or is not directed to neurturin. Thus, the scope has been given for in vitro. In view of the election, the scope is limited to ES cells expressing Pax-4. It is clear from the specification and the art that ES cells will not respond to neurturin. A differentiated cell expressing Pax-4 is needed is needed in vitro to respond to neurturin.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

September 14, 2010